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Guidance on AIDS Drugs for Africa Prepared for Vice President Gore
June 25, 1999

Context: In 1997 South Africa's National Assembly passed legislation granting the Health Minister unspecified powers related to pharmaceutical patents. In response to this legislation, more than 40 companies -- roughly one third from America, one third from Europe, one third from South Africa – challenged the law in South African Court, contending that this law violates the constitution of South Africa. The litigation is still ongoing.

At the same time, the U.S. Trade Representative was concerned that the ambiguity in the law could allow for actions in violation of the WTO-TRIPS agreement (the agreement reached by the 134-member WTO on protection of intellectual property). As a result, USTR named South Africa to the 301 Special Watch List. The watch list (which is not attached to sanctions) is the lowest level of three designations included in the report USTR produces every April. The report's purpose is to signal U.S. concern on intellectual property rights protection offered to U.S. goods by U.S. trading partners.

The Vice President – in his meeting with Deputy President Mbeki in August 1998 -- proposed that the two work toward a solution within a framework that would include parallel importing and compulsory licensing, so long as they were done consistent with international agreements (TRIPS). But progress of negotiations has been slow because of worries on both sides about prejudicing the outcome of the ongoing litigation.

AIDS activists have charged that the Vice President – in order to curry favor with drug companies -- has threatened severe trade sanctions against South Africa. These activists have been given credible airing in the media in spite of underlying facts that disprove their points. Namely: Early in 1999, drug company representatives pushed to raise South Africa's status on the 301 Special Watch List from the lowest level to the highest level. The highest designation – if imposed – would require South Africa to resolve the issue to U.S. satisfaction within a set period of time or face trade sanctions. As reported in a Tuesday, June 22 story in the Baltimore Sun, the Office of the Vice President strongly opposed the drug industry recommendation, and the April 30 report – rather than raising the designation -- kept South Africa on the watch list.

AIDS activists have said the Vice President has threatened trade sanctions against South Africa if they go forward with plans to produce lower-cost AIDS drugs. Is that fair?

- As co-chair of the U.S.-South Africa Binational Commission, the Vice President has made an immense personal investment of time and effort in building better U.S. ties with South Africa – working to improve health, expand trade, build the economy.

- Why would he be trying to undercut his own efforts?

- The Vice President has taken a special interest in South Africa's efforts to fight AIDS, and has kept the crisis clearly in mind as we have worked to resolve our trade differences.

- As Susan Rice, our Assistant Secretary of State for Africa, said in the press this week (Baltimore Sun, Tuesday June 22): the Vice President took the position that the health crisis in South Africa needed to be taken into account, and he led the way led the way in opposing trade sanctions pushed by the pharmaceutical industry.

- These activists – as the Washington Post said in its Thursday editorial – are "manipulating the facts." They should understand that the Vice President is one of the strongest advocates in this administration for the issues they care about.

- They should be working with him instead of against him.

The Vice President cares nothing for millions who are dying.

It would be hard to find someone in the U.S. Government with a more active record of support for the fight against AIDS in South Africa.

Since 1995, the Vice President has co-chaired with Deputy President Mbeki the U.S.-South Africa Binational Commission. In that context, he has had a central role in bringing to South Africa the best of American knowledge, effort and ideas in the fight against AIDS.

Under the auspices of the Commission, the U.S. has funded a South African effort to track the disease –you can't fight it if you can't track it. The Commission has also worked to expand awareness and improve prevention.

The Vice President has brought high-level U.S. health officials on his trips to South Africa – Secretary Shalala and Surgeon General Satcher -- where they have spoken with President Mandela's cabinet on the issue of AIDS.

Just a few months ago, Vice President Gore took Surgeon General David Satcher with him to South Africa for another meeting of the Commission.

When Vice President Gore appeared with Deputy President Mbeki last February on national TV in South Africa, he was wearing an AIDS ribbon, done in African beadwork, given to him by Mbeki after the two had spent hours the previous day in a one-on-one discussion on AIDS.

It is hard to believe that the Deputy President would present the Vice President such a gift unless they were united in partnership in the fight against AIDS.

The Vice President and Deputy President Mbeki spent a substantial part of their time at the press conference talking about the importance of raising awareness of AIDS, and the Vice President urged leaders in every sector of South African society to add their voices to Mr. Mbeki's in the call for greater awareness and action against AIDS.

During those meetings, did the Vice President threaten trade sanctions against South Africa?

No, he did not. The Vice President proposed working toward a resolution within a framework that would include compulsory licensing and parallel importing, as long as they were done in line with international agreements.

What's the basis for the dispute?

The issue arose in 1997, when South Africa's National Assembly passed legislation granting the Health Minister unspecified powers related to pharmaceutical patents. The ambiguity raised concern that actions taken under that law might not be compliant with the WTO-TRIPS agreement.

In response to this legislation, more than 40 companies -- roughly one third from America, one third from Europe, one third from South Africa – have challenged the law in South African Court, contending that this law violates the constitution of South Africa. This case is now being heard by the South Africa Constitutional Court. The ongoing litigation has slowed efforts to resolve it on a government to government level.

But didn't the Vice President order a sweeping new review of South African trade laws on April 30, 1999?

No, he did not. The Baltimore Sun's June 22 story pointed out this fallacy. This charge grows out of a misunderstanding of the United States Trade Representative's Annual 301 report – issued April 30, 1999.

The USTR is mandated by Congress to publish a report every year at the end of April, detailing which of America's trading partners may not be affording full protection to U.S. intellectual property rights. As a result of the passage of amendments to South Africa's Medicines Act, and the provisions that could lead to the loss of U.S. intellectual property rights, the U.S.T.R named South Africa to the "Special 301 watch list." This designation means what it says: "The U.S. is seeing some things that give it concern, signaling that concern to the South African government, and indicating that it will be watching further developments. It is the mildest designation in the report, and is not attached to sanctions.

There are two higher designations on the report -- the priority watch list, and the highest, the priority foreign country list. If a country is named a priority foreign country, it means that the country must -- within a set period of time -- resolve the trade dispute to the satisfaction of the United States or face stiff trade sanctions. South Africa is not close to that status.

But clearly , the Vice President is in the pocket of the pharmaceutical industry

No, he is not. The Pharmaceutical Research and Manufacturers argued this spring that the USTR annual report -- due to come out again at the end of April -- should designate South Africa (because of the Medicines Act) as a priority foreign country, the most severe designation. This would have required South Africa to resolve the issue to U.S. satisfaction within a short period of time, or face sanctions and a loss of foreign aid. As reported in the June 22 Baltimore Sun, the Vice President's office strongly opposed the recommendation. The U.S.T.R. agreed, and its April 30, 1999 report renewed South Africa's status on the watch list.

But the Vice President is trying to stop South Africa from doing things that are legal under WTO/TRIPS.

No, he is not. The U.S. is seeking clarification of the law – about how it will be implemented. The point of discussions has been to work with South Africa to seek assurances that actions taken under the law will be in line with international agreements.

So where does the Vice President stand?

The Vice President believes we need to use all available means to deliver high-quality, affordable medicines to those who need them. And we should do it within the legal limits established by TRIPS. Specifically, the Vice President has no objection to parallel exporting or compulsory licensing of pharmaceuticals in South Africa, so long as it is consistent with TRIPS.

But all the South Africans want to do is what is already their legal right under TRIPS.

Section 15c of the Medicines Act gives the Health Minister unspecified powers that could go beyond was has been agreed to under TRIPS.

But the State Department Report says that the Vice President was part of an effort to put pressure on the South Africans.

First, the State Department report – dated February 5 -- was written in response to members of Congress who had expressed concern that the U.S. wasn't being tough enough with South Africa. They had already suspended U.S. foreign assistance to the central Government of South Africa, and said they would not restore the aid until they received a State Department report detailing what the U.S. was doing to resolve the issue. They had already rejected an earlier report – apparently for not being tough enough.

Second, the only language in the report that names Vice President Gore comes on pages 6 and 7 – under the heading "The Vice President's Plan for a Negotiated Solution." It reads as follows:

"During the August 1998 U.S.-South Africa Binational Commission meetings in Washington, Vice President Gore made the issue of intellectual property rights protection, and pharmaceutical patents in particular, a central focus of his discussions with Deputy President Mbeki. They agreed on a basis for a mutually satisfactory, Government-to-Government negotiated solution to the impasse."

That is the only mention of Vice President Gore's actions in the entire report.

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WASHINGTON -- It is an unlikely first issue of the 2000 presidential campaign: the AIDS epidemic in South Africa, and whether Vice President Al Gore has helped block the production and importation of cheap, generic AIDS drugs to southern Africa.

But three jarring protests at Gore appearances last week have pushed the issue to the front of the vice president's consciousness, infuriating Gore's White House staff and raising the stakes when AIDS activists meet today with the White House AIDS czar.

The activists have pledged to disrupt Gore's campaign events until they win a shift in administration trade policy, which they say favors the powerful pharmaceutical industry over the life-and-death needs of Africa's poor. Protesters say Gore has led a White House drive to force South Africa to scuttle an effort that would bypass U.S. patent laws to provide life-saving medicine to many Africans dying of AIDS.

"Gore has been carrying out the dirty work of the pharmaceuticals companies," said Eric Sawyer, co-founder of the AIDS group ACT UP New York. "He's putting a higher priority on trade than public health."

But Gore aides -- and even some AIDS activists -- say the protesters have distorted the vice president's efforts to forge a compromise between protecting U.S. patent law and addressing an AIDS crisis in southern Africa. Susan Rice, the assistant secretary of state for Africa, asserted that Gore has "led the way" in opposing trade sanctions and other drastic actions pushed by the pharmaceutical industry.

"The root of what is wrong in AIDS care is drug pricing, but the vice president is not the culprit -- the drug companies are," said Daniel Zingale, executive director of the AIDS Action Council, the nation's largest lobby on AIDS issues. "Of all the people running for president, Gore seems like an unlikely one to target."

To many AIDS activists, the issue is simple: South Africa wants to lower the price of AIDS treatments, and Gore is trying to block those efforts. Three times last week, protesters disrupted his rallies with taunts and signs proclaiming, " Gore's Greed Kills." A rally is planned Monday in Philadelphia outside a hotel where Gore will be raising campaign cash.

"We're not going to go away until this administration changes its policy," Sawyer said.

Drug companies cry foul

In 1997, South Africa passed a law granting its health minister authority to let local pharmaceutical companies produce generic versions of AIDS drugs, despite U.S. patents on those drugs. With 3.2 million South Africans infected with HIV, and the price of AIDS drugs out of reach for most of them, the government called its actions necessary and legal.

But U.S. and European drug companies cried foul. They rushed to Congress and the U.S. trade representative for help, and to court in South Africa to try to block the law. Industry executives won an injunction.

With the cost of drug development soaring to up to $500 million for one new medication, patent rights have become critical to companies' survival, industry officials say.

"Patent protection is vitally important to this industry," said Jeff Trewhitt, a spokesman for Pharmaceutical Research and Manufacturers of America, or Pharma, the industry's lobbying arm.

At the industry's behest, Rep. Rodney Frelinghuysen, a New Jersey Republican, slipped language into last year's budget law requiring the State Department to report to Congress on its efforts to suspend or repeal the South African law. In the meantime, no U.S. foreign aid could be released to South Africa's government.

The State Department came back with a report in February that is now haunting Gore. The report said the nation was "making use of the full panoply of leverage in our arsenal," including the vice president, to gut the South African law. Gore had made the issue "a central focus" of his meeting with then-South African Deputy President Thabo Mbeki in August, the report stated. Gore met with Mbeki in February and again brought up the issue. To the AIDS activists, this document was the smoking gun.

"Since Gore is the orchestrator of this whole policy, we plan to continue," said Asia Russell, a member of ACT UP Philadelphia. "We're going to escalate until these policies change."

Wrong about role, aides say

But Gore aides say the activists are wrong about his role. Leon S. Fuerth, the vice president's national security adviser, who attended both meetings with the future South African president,said Gore offered to discuss an import agreement to let South Africa shop for the best price for AIDS drugs worldwide and then import them in bulk. The offer "would likely be controversial with the drug companies," Fuerth said, but Gore favored "a mutually acceptable solution."

And Gore aides said AIDS activists are bending other facts. In an open letter to Gore, for instance, activists asserted that he had authorized the U.S. trade representative to conduct "a sweeping new review of South Africa policies" on April 30.

In fact, the April 30 report was the U.S. trade representative's annual report on intellectual property rights that looked at more than 70 countries. Gore had nothing to do with it. South Africa was one of 37 countries placed on the trade representative's "watch list," the lowest-priority category.

Trewhitt acknowledged that the pharmaceutical industry pushed the administration to label South Africa a "priority foreign country," which would set a deadline for it to change its disputed policy before trade sanctions would take effect. But under pressure from Gore's office, the trade representative refused to do so.

"The vice president took the position that the health crisis in South Africa really needed to be taken into account," Rice said.

But AIDS activists remain unconvinced.

Gore's deputies "want it both ways," said James Love, director of the Consumer Project on Technology and a leading Gore critic on the issue. "They want to sit around with Pharma, negotiate for campaign contributions, then blame everything on Rodney Frelinghuysen ."

The activists concede that their actions may be shortsighted. Gore has been generally friendly to AIDS groups, pushing for more spending on AIDS research and patient care. Sawyer noted that ACT UP's 1994 campaign against incumbent New York Gov. Mario M. Cuomo might have turned off gay and minority voters, helping elect George E. Pataki, a Republican who, Sawyer says, has been far less attentive.

"But this is a crisis of huge proportions," Sawyer said. " This is a genocide of 30 million to 40 million people of color. It cannot be seen as anything else."

GRAPHIC: PHOTO(S) Homecoming: Vice President Al Gore and his wife, Tipper, listen to speakers at the annual Family Re-Union conference in Nashville, Tenn., where he repeated the values theme he used to launch his campaign.